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10/595,868	01/11/2007	Nicolas Eric Faucher	PB60570USW	8239

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EXAMINER	
FIERRO, ALICIA	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
07/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/595,868	FAUCHER ET AL.	
	Examiner	Art Unit	
	Alicia L. Fierro	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22,23,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *17* is/are allowed.

6)☒ Claim(s) *1-15,18,22,23,26 and 27* is/are rejected.

7)☐ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/17/06 and 6/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-18, 22, 23, 26 and 27 are pending in the instant application, filed May 17, 2006.

Priority

2. The instant application is a national stage entry of PCT/EP04/012965, filed November 15, 2004, which claims the benefit of UK0329462.6, filed December 19, 2003 and UK 0326747.3, filed November 17, 2003. Insofar as the instant claims are not enabled for "solvates" of claimed compounds or for the claimed methods of treatment (see rejections below), claims 1-15, 22, 23, 26 and 27 do not have support in the priority document, and the claims are therefore examined with an effective filing date of November 15, 2004.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on May 17, 2006 and June 29, 2006 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, these IDS documents were considered and signed copies of form 1449 have been enclosed herewith.

Claim objections

4. Claim 16 is objected to because the Markush language used in many of the substituent definitions is improper. When using the word "is" or the phrase "selected from," the various substituent definitions should be separated by the word "or." When using the phrase "selected from the group consisting of," the substituent definitions should be separated by the word "and." See MPEP 2173(h). As such, "and" should be changed to "or" in the objected claim. Appropriate correction is required

Claim Rejections - 35 USC § 112

(second paragraph)

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a method of treating a hPPAR mediated disease or condition. No explicit definition of the diseases/conditions to be treated is provided in the disclosure and a person of ordinary skill in the art would not have the necessary information to determine what subject matter Applicants intend to encompass with the instant claim. With regards to an explanation of this phrase, the only guidance provided by the specification is in the form of a non-limiting list of diseases on page 3, lines 19-29.

7. This rejection can be overcome by cancellation of the rejected claim, reciting particular diseases (which are supported by the disclosure) to be treated in the claim, or inserting the limitations from claim 27 into claim 26.

Claim Rejections - 35 USC § 112

(First Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 26 is drawn to a method of treating "a hPPAR mediated disease or condition" which does not appear to be supported by the specification. Firstly, the phrase is used without specifically stating whether the activity of the claimed compounds would be inhibitory or activating. One class of compounds would not reasonably be expected by a person of ordinary skill in the art to have *both* agonistic and antagonistic activity on the same receptor; thus, this language does not have support.

Additionally, the recitation of "a hPPAR mediated disease or condition" does not have sufficient written description. Based on the disclosure, the entirety of diseases/conditions

intended to be encompassed by this term/claim (other than those specifically disclosed and claimed disorder, e.g. in claim 27) would not be known to a person of ordinary skill in the art. Applicants describe no "hPPAR mediated disease or conditions" other those specifically disclosed as examples and claimed in claim 27. Assays are described for determining if a particular compound of the invention is able to activate several PPAR subtypes, but no assay is described for determining if a particular disease or condition is mediated by the receptor nor are any *in vivo* assays conducted to demonstrate that the compounds have the claimed activity when administered in the claimed method. Further, the instant claim is drawn to both known conditions and conditions that have not yet been discovered to be affected by hPPAR activity. It would not be reasonable for a person of ordinary skill in the art to conclude that Applicants were in possession of all of these diseases/conditions (including those that are yet to be known) based on the disclosure provided. As such, no conditions mediated by hPPAR receptor activity, other than those described in the examples provided or claim 27, are described adequately enough to allow one skilled in the art to ascertain that Applicant is in possession of the entire scope of the claimed genus. Applicants have not described the genus in a manner that would allow one skilled in the art to immediately envisage all the diseases/conditions contemplated for use. Thus, the claims lack adequate written description for the myriad of conditions embraced by the claimed "hPPAR mediated disease or condition."

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention

achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

9. Claims 1-15, 18, 22-23 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling salts and esters thereof, as well as a method of treating some of the claimed conditions, does not reasonably provide enablement for solvates of the claimed compounds, for the treatment of all hPPAR mediated diseases/conditions, or for the treatment of *any* hPPAR mediated diseases/conditions when the definition of treatment provided in the disclosure is used. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. The nature of the invention
2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present

5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed, and
8. The level of skill in the art

(a) Wands analysis for solvates

The Nature of the Invention

The instant invention is drawn to a compound of Formula (I), as well as salts, hydrolysable esters and solvates thereof, as well as pharmaceutical compositions of the claimed compounds..

The State of the Prior Art and the Predictability or lack thereof in the art

Active pharmaceutical ingredients are frequently delivered to the patient in the solid-state as part of an approved dosage form (e.g., tablets, capsules, etc.). Solids provide a convenient, compact, and generally stable format to store an active pharmaceutical ingredient or a drug product. Understanding and controlling the solid-state chemistry of active pharmaceutical ingredients, both as pure drug substances and in formulated products, is therefore an important aspect of the drug development process. Active pharmaceutical ingredients can exist in a variety of distinct solid forms, including polymorphs, solvates, hydrates, salts, co-crystals, and amorphous solids. Each form displays unique physicochemical properties that can profoundly influence the bioavailability, manufacturability purification, stability, and other performance characteristics of the drug. Hence, it is critical to understand the relationship between the particular solid form of a compound and its functional properties.

For ionizable compounds, preparation of salt forms using pharmaceutically acceptable acids and bases is a common strategy to improve bioavailability. However, the preparation of other solid

forms such as polymorphs and solvates are not so common as to be predictable. In order to obtain patent protection on these forms, some of which may have significantly different properties and relevance as development candidates, it is essential to prepare them, identify conditions for making them, and evaluate their properties as valuable new pharmaceutical materials. A large number of factors can influence crystal nucleation and growth during this process, including the composition of the crystallization medium and the processes used to generate super-saturation and promote crystallization (Morissette et al. *Advanced Drug Delivery Reviews* 2004, 56, 275-300). Therefore, for these reasons, the state of the prior art is one of unpredictability.

As stated above, crystalline solids can exist in the form of polymorph, solvates or hydrates. "Phase transitions such as polymorph interconversion, desolvation of solvate, formation of hydrate, and conversion of crystalline to amorphous form may occur during various pharmaceutical processes, which may alter the dissolution rate and transport characteristics of the drug. Hence, it is desirable to choose the most suitable and stable form of the drug in the initial stages of drug development" (Vippagunta et al. *Advanced Drug Delivery Reviews* 2001, 48, 3-26, abstract). In further discussing the predictability of the formation of solvates, Vippagunta et al. discloses that "predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds" (page 18, section 3.4).

The Amount of Direction or Guidance Present and Presence or Absence of Working Examples

The only direction or guidance present in the instant specification is for compounds of claim 1, as well as pharmaceutically acceptable salts and pharmaceutical compositions. There is no data present in the specification for the preparation of solvates of compounds of claim 1. The specification only discloses that "compounds of the present invention may also be utilized in the form of a...solvate thereof" [¶ 0109]. The guidance in the specification is limited to the disclosure that certain compounds can exist in solvated form; however, it is not discussed which specific compounds can exist in this form, or which particular solvated form Applicant intends to claim as their invention. Additionally, preferred embodiments and examples do not support enablement for solvates of *certain* compounds. Finally, there are no working examples present in the disclosure for the preparation of any particular solvates. In each of the working examples, the compound is placed in solution, but ultimately dried, and although crystallization from a solvent is mentioned in some examples, there is no direction as to which solvates are ultimately produced.

The Breadth of the Claims

The instant breadth of the rejected claims is broader than the disclosure, specifically; the instant claims include any solvates of the claimed compounds.

The Quantity of Experimentation Needed and the Level of Skill in the Art

While the level of skill in the pharmaceutical arts is high, it would require undue experimentation for one of ordinary skill in the pertinent art to prepare *any* solvate of the compounds of the rejected claims. The science of crystallization has evolved such that, without guidance or

working examples in the specification, the claims lack enablement. This rejection can be overcome by deletion of the word "solvates" from the rejected claims.

(b) Wands analysis for methods of treating

The Nature of the Invention and Breadth of the Claims

Instant claims 26-27 are drawn to a method of treating diseases or conditions which are mediated by hPPAR, including those specifically claimed in claim 27. According to the instant specification at p.13, line 25: "reference to treatment extends to prophylaxis." Thus the method also includes prevention or prophylaxis of the claimed diseases.

The prophylaxis or "prevention" actually means to anticipate or counter in advance, to keep from happening, etc. and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds and compositions can be administered in order to have the "preventive" effect for a patient suffering or susceptible to any of the claimed diseases/conditions.

Specifically, for example, syndrome X (which is also commonly known as metabolic syndrome) and cardiovascular diseases are specifically claimed as diseases to be treated/prevented.

The term "metabolic syndrome" could be broadly interpreted to encompass any abnormality that results in the alteration of the normal metabolism of carbohydrates, lipids, proteins, nucleic acids, etc. within a patient, and complications thereof could read on a seemingly endless and extremely broad group of characteristics. The specification refers to syndrome X as

being "loosely defined," (p.1). Consistent with this broad interpretation is the large list of diseases set forth in the specification that Applicants state are included in the "hPPAR mediated diseases" which can be successfully treated using compounds of formula I (e.g., see page 3, lines 19-29). For example, syndrome X and cardiovascular diseases are extremely broad terms and encompass many diseases which have not been specifically identified in the instant application. Thus, in order to be enabled, the specification must teach how to use the compounds as set forth in claim 1 for at least the treatment of the many diseases encompassed by the language of the instant claims.

In addition, to this non-limiting list of diseases, it is noted that metabolic syndrome is characterized in the art by a group of many "metabolic risk factors" that a person may have, including abdominal obesity, atherogenic dyslipidemia, elevated blood pressure, insulin resistance or glucose intolerance, prothrombotic state, and proinflammatory state (American Heart Association, "Metabolic Syndrome" <http://www.americanheart.org/presenter.jhtml?identifier=4756>, page 1). Consequently, it is noted that there is no universally accepted medical definition for exactly what characterizes metabolic syndrome or a metabolic disturbance (American Heart Association, page 1). Consistent with this position, is the World Health Organization which presents yet another slightly different and slightly broader characterization of metabolic syndrome than the criteria set forth by the 2001 National Cholesterol Education Program Adult Treatment Panel (ATP III) (Mathur, "Metabolic Syndrome," see section "How is metabolic syndrome defined?" <http://www.medicinenet.com/metabolic_syndrome/article.htm>, pages 2-3). As a result, the claimed methods may actually read on a much larger list than those set forth on page 3 of the

specification. Consequently, the nature of the invention and the breadth of the claims cannot be fully determined.

The Amount of Direction / Guidance Present and the Presence or Absence of Working Examples

The specification fails to set forth sufficient working examples of the claimed invention. That is, the specification does not show any examples where the compounds of the instant invention were used to treat any diseases mediated by hPPAR or provide evidence that the compounds were even administered for the claimed use. See MPEP 2164.02 ("Compliance with the enablement requirement of 35 USC 112, first paragraph, does not turn on whether an example is disclosed … Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art."). The specification merely sets forth binding assays for a few PPAR subtypes, which are not "reasonably correlated" to the vast numbers of diseases encompassed by the claims. See MPEP 2164.02 ("The issue of "correlation" is related to the issue of the presence or absence of working examples. "Correlation" as used herein refers to the relationship between in vitro … assays and a disclosed or a claimed method of use. An in vitro … example, in the specification, in effect, constitutes a "working example" if that example "correlates with a disclosed or claimed method invention. If there is no correlation, then the examples do not constitute "working examples." … For a claimed genus [e.g., metabolic disorders or hPPAR mediated diseases], representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art … would expect the claimed genus could be used in the manner without undue experimentation"). While Applicants do indeed make various statements in the specification that their claimed compounds will effectively treat the genus of claimed diseases, such is not

supported by conclusive examples. For instance, no *in vivo* data is provided for *any* of the claimed compounds in treating or preventing *any* of the claimed diseases. Based on the disclosure and examples, the claimed compounds were not administered to humans for their preventative or therapeutic effects on the myriad of claimed diseases. Thus, the disclosure and examples do not reasonably correlate with the large number of diseases that fall with the scope of hPPAR mediated diseases or conditions, including syndrome X and cardiovascular diseases. That is, the limited testing set forth in the assays does not constitute a "working example" within the meaning of MPEP 2164.02 let alone a "representative" set of examples that would be required the describe this enormous genus.

The State of the Prior Art and the Predictability or lack thereof in the art

The state of the art at the time of this application is that the etiology and treatment of all diseases or conditions associated with hPPAR is not well understood. Treatment of hPPAR related disorders and conditions is challenging and highly unpredictable. Adding to the challenge are the many different diseases that could be encompassed by hPPAR and all the different mechanisms of action and no two types of hPPAR related disease could be said to share the same method of treatment.

Currently, three mammalian Peroxisome Proliferator-Activated Receptors have been isolated and termed PPAR-alpha, PPARgamma, and PPAR-delta (also known as NUC1 or PPAR-beta). These PPARs regulate expression of target genes by binding to DNA sequence elements, termed PPAR response elements (PPRE). To date, PPRE's have been identified in the enhancers of a number of genes encoding proteins that regulate lipid metabolism suggesting that PPARs play a pivotal role in the adipogenic signaling cascade and lipid homeostasis.

The use of PPAR agonists to treat dyslipidemia has been known for several decades because of their triglyceride lowering and high density lipoprotein cholesterol elevating effects. The use of PPAR agonists to treat cardiovascular disorders is being researched and has a promising future, but it is unclear whether they will indeed be used in treating cardiovascular disorders until more research is done. Raalte et al., *Pharm. Res.*, Vol. 21(9), September 2004, pp. 1531-1538, especially p. 1536.

Grundy et al. discloses that "a lack of understanding of the genetic and metabolic contributions to the causation of the syndrome stands in the way of developing new therapeutic approaches." And further that there is therefore a need for "additional basic and clinical research designed to better understand pathophysiology from the standpoint of genetics, molecular biology, and cellular signaling" (Grundy et al. *Circulation* 112 (2005), page 2745, first paragraph). Grundy et al. conclude that "considerable additional research is needed to better refine the most appropriate therapies for individuals with metabolic syndrome" (see Conclusions, p. 2745, #7). Thus, Grundy et al. demonstrates that the treatment of metabolic disorders is an unpredictable art.

Even the more narrowly claimed diseases and conditions have been demonstrated to be unpredictable with regards to their prevention and, in some cases, their treatment. For example, regarding obesity Molnar ("New drug policy in childhood obesity," 2005, International Journal of Obesity, 29:S62-S65) teaches that excessive fatness has undoubtedly become the primary childhood health problem in developed nations (p. S62, 1st paragraph). While the results of two studies involving adolescents with sibutramine are promising, the duration of the studies was too short and the number of patients included was low, larger and longer studies are needed to assess

the benefits and hazards of sibutramine treatment in obese adolescents (p. S63, right, 1st paragraph). Orlistat has been approved as medication for obesity in obese adolescents (p. S63, right, 1st paragraph). Hundreds of molecules are currently under investigation as treatments for obesity, but there is currently only one drug approved for the treatment of obesity in adolescents, for example. Considering that only one drug out of the hundreds that have been studied has been approved for actual use in treatment, the art can be considered unpredictable with respect to the development of new drug therapies for treating obesity, let alone how much less predictable would be the ability to prevent the development of obesity in an individual who is not yet obese.

The claimed "cardiovascular disease" is a term which is interchangeable with heart disease, which is defined as "a broad term used to describe a range of diseases that affect your heart, and in some cases, your blood vessels." The term encompasses a wide range of disorders, including diseases of the blood vessels (e.g. coronary artery disease), heart rhythm problems (arrhythmias), and congenital heart defects which an individual is born with. Additionally, other conditions such as infections or conditions affect the heart's muscle, valves, or beating rhythm are considered to be forms of heart disease. Thus, the claimed term encompasses not only diseases immediately resulting from Metabolic Syndrome, but also conditions that an individual could be born with. It is established that there is no way to prevent a congenital heart defect and additionally, one class of compounds (e.g. hPPAR agonists) could not reasonably be expected to be effective in the treatment of the wide variety of diseases encompassed by the claimed cardiovascular diseases, including not only diseases associated with arterial blockage but also congenital heart defects.

Consequently, a person of skill in the art would not reasonably expect a very limited number of *in vitro* PPAR binding to reasonably translate to therapeutic effects in humans, or to "reasonably correlate" with the hundreds of claimed disease treatments. That is, Applicants limited disclosure is not representative of this enormous genus especially when said genus encompasses a large amount of unpredictable art.

The level of the skill in the art

The level of skill in the art is high, with the skilled artisan typically having an advanced degree such as a Ph.D. or MD.

The quantity of experimentation needed

As a result of the broad and unpredictable nature of the invention and the lack of specific guidance from the specification, it is respectfully submitted that the quantity of experimentation needed to make and or use the invention would be great. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 * n.23 (Fed. Cir. 19991). Also note that the amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. *In re Fisher*, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. *In re Fisher*, 427 F.2d 839, 166 USPQ 24; *Ex Parte Hitzeman*, 9 USPQ 2d 1823. Here, in view of the Wands factors and *In re Fisher* (CCPA

1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated or prevented by the compound encompassed in the instant claims, with no assurance of success.

Conclusion

In conclusion, the specification fails to provide sufficient support of the broadly claimed hPPAR mediated diseases or conditions, as a result necessitating one of skill to perform an exhaustive search for which compounds, if any, could prevent and treat the claimed diseases in order to practice the claimed invention. "A patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001.

Conclusion

10. Claim 17 is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Fierro whose telephone number is (571)270-7683. The examiner can normally be reached on Monday - Thursday 6:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia L. Fierro/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626